

127

9

No. 08-1202

Supreme Court, U.S.
FILED

APR 24 2009

OFFICE OF THE CLERK

In The
Supreme Court of the United States

IMS HEALTH, INC. and VERISPAN LLC,

Petitioners,

v.

KELLY M. AYOTTE, as Attorney General
of the State of New Hampshire,

Respondent.

On Petition For A Writ Of Certiorari
To The United States Court Of Appeals
For The First Circuit

BRIEF OF COUNCIL OF AMERICAN
SURVEY RESEARCH ORGANIZATIONS, INC.
AND PHARMACEUTICAL MARKETING
RESEARCH GROUP, INC. AS AMICI CURIAE
SUPPORTING THE PETITIONERS'
PETITION FOR WRIT OF CERTIORARI

DUANE L. BERLIN
Counsel of Record
E. BARRY LYON
LEV & BERLIN, P.C.

200 Connecticut Avenue
5th Floor
Norwalk, CT 06854
(203) 838-8500

*Counsel for Amici Curiae
Council of American
Survey Research
Organizations, Inc.*

MICHAEL SLOTZNICK
1020 Little Shiloh Road
West Chester, PA 19382
(484) 887-0497

*Counsel for Amici Curiae
Pharmaceutical Marketing
Research Group, Inc.*

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
INTEREST OF AMICI CURIAE.....	1
SUMMARY OF ARGUMENTS	6
ARGUMENTS.....	8
I. The Prescription Information Law and the First Circuit's Ruling Effectively Terminate the Petitioners' Subject Lines of Business for the Sole Purpose of Placing Restrictions on Communications Between Pharmaceutical Detailers and Physicians	8
II. The Prescription Information Law and the First Circuit's Ruling Fail to Consider the Varied Uses of Prescriber-Identifiable Information and the Varied Businesses and Industries Using and Relying on Prescriber-Identifiable Information, thus Wrongfully Depriving Those Users of Those Uses	11
III. The First Circuit's Ruling Establishes Precedents that Would Permit State and Federal Governments to Restrict and/or Censor Other Reliable, Legitimate and Truthful Information Subject to a Significantly Reduced Level of Judicial Scrutiny	14
CONCLUSION.....	17
APPENDIX A	
A. CASRO: "Who We Are, What We Do"	App. 1

TABLE OF AUTHORITIES

	Page
CASES	
<i>Andrews v. Eli Lilly & Co.</i> , 97 F.R.D. 494 (N.D. Ill. 1983)	5
<i>Central Hudson Gas & Electric Corp. v. Public Services Comm'n of NY</i> , 447 U.S. 557 (1980).....	15
<i>Cimino v. Raymark Industries, Inc.</i> , 751 F. Supp. 649 (E.D. Tex. 1990)	5, 6
<i>Dow v. Allen</i> , 672 F.2d 1262 (7th Cir. 1982)	5
<i>Federal Communications Commission and United States v. Beach Communications, Inc., et al.</i> , 508 U.S. 307 (1993).....	15
<i>IMS Health, Inc. v. Kelly A. Ayotte, New Hampshire, Attorney General</i> , 550 F.3d 42 (1st Cir. 2008)	7, 11, 15
<i>Lehnhausen v. Lake Shore Auto Parts Co.</i> , 410 U.S. 356 (1973).....	15
<i>Lyng v. Automobile Workers</i> , 485 U.S. 360 (1988).....	15
STATUTES	
The Prescription Information Law, 2006 N.H. Laws 328 (Codified at N.H. Rev. Stat. Ann. §§ 318:47-f, 318:47-g, and 318:-B12, IV)	<i>passim</i>

TABLE OF AUTHORITIES – Continued

	Page
OTHER AUTHORITIES	
H. Barksdale, <i>The Use of Survey Research Findings As Legal Evidence</i> (1957)	4
W. Finfrock & D. Spradlin, <i>How to Organize and Present Statistical Evidence</i> , 24 Prac. Law. 67 (1978)	4
M. Finkelstein, <i>Quantitative Methods in Law</i> (1978)	4
I. McCarthy, <i>Trademarks and Unfair Competition</i> (2nd Ed. 1978)	4

INTERESTS OF AMICI CURIAE¹

Council of American Survey Research Organizations, Inc. ("CASRO").

CASRO is a not-for-profit trade association representing over three hundred (300) United States survey research companies engaged in professional survey research regarding a wide variety of technical, scientific, pharmaceutical, health care, economic, and other public and private issues. The survey research companies' clients include virtually every manner of for-profit, not-for-profit and governmental entity. See Appendix A. CASRO's members are in aggregate responsible for the overwhelming majority of the survey research, including pharmaceutical survey research, conducted each year in the United States. CASRO was formed for the purposes of creating certain values and standards for the survey research industry and establishing a spokesperson to represent the interests of the survey research industry. CASRO's principle functions are (1) to promote a rigorous code of conduct that enhances the image of survey research and protects the public's rights and privacy; (2) to advocate the survey research industry's effective

¹ All counsel of record received written notice of Amici's intention to file this brief, at least ten (10) days before this brief was due. This brief is filed with the written consent of all parties, which consents are filed herewith. No counsel for any party authored this brief, whether in whole or in part, nor did any person or entity, other than Amici or their counsel, make a monetary contribution to the preparation of this brief.

self-regulation when legislators propose bills that threaten legitimate survey research; and (3) to champion legitimate research companies and marginalize disreputable research companies that threaten or attempt to threaten the survey research industry's reputation. *See Appendix A.* A vast majority of CASRO's members work, whether directly or indirectly, with the pharmaceutical, medical and health care industries conducting legitimate survey research designed to improve treatment options and patient care; and improve and develop pharmaceutical products and medical devices. This case and its proper resolution are of great importance to CASRO, as upholding the New Hampshire Prescription Information Law (*see 2006 N.H. Laws § 328, codified at N.H. Rev. Stat. Ann. §§ 318:47-f, 318:47-g, 318-B:12(IV) (2006)* (referred to hereinafter as the "Prescription Information Law")) would (1) threaten the legitimate business activities of Petitioner IMS Health, Inc., a CASRO member; (2) threaten legitimate pharmaceutical survey research by eliminating a valuable information and data resource; and (3) threaten the permitted uses of other reliable, truthful and lawfully obtained information, which, similar to the data and information at issue in this case, are essential to CASRO and its membership in the performance of legitimate survey research, including without limitation pharmaceutical survey research. Additional information about CASRO can be found at <http://www.casro.org/>.

Pharmaceutical Marketing Research Group, Inc. ("PMRG")

PMRG is a not-for-profit trade association whose members consist of over eight hundred (800) individual employees of (a) marketing research companies and (b) manufacturers of pharmaceutical, biotech, medical device and other health care products who commission the services of such research companies. PMRG's purpose is to promote the use and quality of marketing research for and by such manufacturers (referred to generally herein as "pharmaceutical marketing research," and for present purposes generally tantamount to pharmaceutical survey research). PMRG'S principal activities consist of (1) providing educational and other collaborative forums where employees of such manufacturers and their marketing research suppliers meet; (2) promoting technical knowledge and ethical standards for the conduct of pharmaceutical marketing research; and (3) advocating on government affairs issues of concern to PMRG's membership. PMRG considers pharmaceutical marketing research to be of great positive social impact. Among many other benefits to American society, pharmaceutical marketing research has been a significant driver in the development and improvement of medical devices, drugs and services. Many life-improving and life-saving solutions owe their existence to such research, whether through the creation of new products or through better delivering existing treatments. Many (individual) researcher-side members of PMRG are employed by (corporate)

members of CASRO, including by Petitioner IMS Health, Inc., while several PMRG members are employed by Petitioner Verispan LLC's parent, SDI Health LLC. This case and its proper resolution are of importance to PMRG for the same reasons they are important to CASRO, as stated above. Additional information about PMRG can be found at <http://www.pmrg.org/>.

The Survey Research Industry

The survey research industry, of which Amici and their membership are a part, is a well respected and important fixture of the commercial landscape that is essential to the development and improvement of health care in the United States and other countries. Survey research serves an important function throughout our society² and is utilized by universities (in the fields of medicine and social sciences, for example), corporations, research institutes, litigants, as well as governmental agencies, to assist in the analyses of technical, scientific, economic, health care, pharmaceutical, and other social, commercial,

² See generally M. Finkelstein, *Quantitative Methods in Law* (1978), quantitative techniques of proof as applied in various legal claims; H. Barksdale, *The Use of Survey Research Findings as Legal Evidence* (1957) (same); W. Finfrock & D. Spradlin, *How to Organize and Present Statistical Evidence*, 24 Prac. Law. 67, 67-68 (1978), antitrust evidence increasingly economic and statistical; I. McCarthy, *Trademarks and Unfair Competition*, Section 32:46 ff. (2d ed. 1984), important and growing role of survey evidence.

scientific and public policy issues. No other tool permits these societal constituencies to obtain comparable data and related information. Without such data many issues affecting both public and private interests could not be addressed as intelligently or resolved as reliably. There is, as one court rightly summarized the situation, "undoubtedly a compelling social interest in promoting [survey] research." *Andrews v. Eli Lilly & Co.*, 97 F.R.D. 494, 500 (N.D. Ill. 1983). See also, *Dow v. Allen*, 672 F.2d 1262 (7th Cir. 1982). In *Cimino v. Raymark Industries, Inc.*, 751 F. Supp. 649 (E.D. Tex. 1990), the court articulated the value of survey data as a unique and important research tool:

"... the science of statistics is now universally accepted, exerting the most profound influence on our daily lives. 'The objective of statistics is to make an inference about a population of interest based on information obtained from a sample ... of that population.' For example, statistical sampling plays a critical role in medical and pharmaceutical research ... [a]s in medical research, private industries employ statistical techniques in the development and testing of new products ... [it is used] for many diverse tasks, such as maintaining the dimension requirements for the plastic cards used in automatic bank teller machines or testing the specific gravity of laundry detergent. Statistical techniques are particularly valuable in the field of marketing ... the insurance industry ... education ... in the

administration and evaluation of various standardized tests . . . [and] in the political arena." *Id.* at 660.

The judicial process itself is a significant beneficiary of survey and public opinion research. In *Cimino*, it was reported that " . . . [a]cceptance of statistical evidence is now commonplace in the courts . . . , it occurs frequently in Title VII employment discrimination cases, most often demonstrating a pattern or practice of discrimination on the part of the employer . . . , it has been used in anti-trust cases to project pre and post merger market share and market concentration. . . . [and] in trademark infringement suits [it] is useful in determining consumer product identification and confusion regarding trademarks. . . ."

SUMMARY OF ARGUMENTS

The Prescription Information Law and the decision of the United States Court of Appeals for the First Circuit (the "First Circuit") (1) lay the foundation for the unfair and legally improper termination of the Petitioners' subject lines of business – not only in New Hampshire, but throughout the United States, as two additional states currently have enacted laws restricting the use of prescriber-identifiable and patient-identifiable information, and numerous other state legislatures have proposed and are considering similar legislation during this current legislative calendar period, all as a direct result of the Prescription Information Law, for the sole purpose of placing

restrictions on the communications between pharmaceutical detailers³ and physicians; (2) fail to consider the varied uses of, and varied businesses and industries relying on and benefiting from, prescriber-identifiable information; and (3) open the door for unchecked governmental regulation of other forms and types of reliable, legitimate and truthful speech (i.e. reliable, legitimate, and truthful information), which would have a devastating effect on businesses and industries relying on the availability of such information and on the general public who are the beneficiaries of the products and services provided by such businesses and industries. Amici, therefore respectfully request this Court to grant the Petitioners'

³ The subtle differences in the explanations of “detailing” as described in the First Circuit’s Majority Opinion and Judge Lipez’s Concurring/Dissenting Opinion highlight the differing societal value placed on “detailing.” The Majority Opinion explains detailing as follows: “Pharmaceutical sales representatives, known in industry argot as ‘detailers,’ earn their livelihood by promoting prescription drugs in one-on-one interactions with physicians.” *IMS Health, Inc. v. Kelly A. Ayotte*, 550 F.3d 42, 44 (1st Cir. 2008). The Majority Opinion further elaborates that “If a physician’s prescribing habits present an appropriate opportunity, the detailer attempts to gain access to the physician’s office, usually by representing herself as a helpful purveyor of pharmaceutical information and research.” *IMS Health, Inc.* at 46. Judge Lipez’s Concurring/Dissenting Opinion explains “detailing” as follows: “Detailing is the face-to-face advocacy of a product by sales representatives who visit doctors’ offices and hospitals to meet with prescribing health care professionals. Although the objective of these visits is to make sales, detailers often provide valuable information about the drugs they are selling.” *Id.* at 71.

writ of certiorari and reverse the First Circuit's ruling.

ARGUMENTS

I. The Prescription Information Law and the First Circuit's Ruling Effectively Terminate the Petitioners' Subject Lines of Business For the Sole Purpose of Placing Restrictions on Communications Between Pharmaceutical Detailers and Physicians.

The Petitioners are in the pharmaceutical market intelligence business, an area of pharmaceutical market research, and they provide certain products and services that address a variety of needs within the pharmaceutical, medical and health care industries. As noted above, Petitioner IMS Health, Inc. is a valued member of Amicus CASRO in good standing, and to CASRO'S knowledge it upholds CASRO's standards of professional and ethical conduct. The products and services at issue in this case involve the Petitioners' purchase of reliable, legitimate and truthful information (i.e. prescriber-identifiable information) from pharmacies and other sources; the deletion or removal of any data or information that may identify an individual patient; the aggregation of the prescriber-identifiable information with other information that is either available to the general public or obtained through a license with a third party, but that in any event is likewise

devoid of patient identities; and the creation of prescriber reference files. The prescriber reference files are then sold, licensed or transferred by the Petitioners to individuals and/or entities, including without limitation pharmaceutical survey researchers, pharmaceutical companies, and certain not-for-profit entities or groups, including without limitation educational institutions, public interest groups, and law enforcement agencies. The purchasers of that data use the information to better understand individual, national and international prescribing behavior, so as to promote their respective for-profit or not-for-profit purposes.

While Amici acknowledge that the Petitioners (like all other businesses) should not and do not have an unlimited right to conduct their respective business activities, the Petitioners' subject business activities now stand to be, but should not be, completely terminated as a result of, or radically restricted by, legislative efforts to limit the use of prescriber-identifiable information by one class of recipients or end-users of such information – the pharmaceutical manufacturers in the "detailing" and other direct marketing operations described below. The Petitioners are a source of reliable, legitimate and truthful information that has many uses, as discussed herein, other than pharmaceutical detailing or direct marketing of pharmaceutical products performed by those end-users who are the target of the Prescription Information Law, and thus termination of the

Petitioners' business lines is unfair, unnecessary, and draconian toward the Petitioners.

This unfair and unnecessary legislative approach has been followed by two states (i.e. Maine and Vermont) that have enacted, and numerous other state legislatures currently considering, legislation similar to the Prescription Information Law. The Petitioners have legally challenged both the Vermont and Maine statutes; the Vermont statute is currently under judicial review and the Maine statute has been struck down. This Court's ruling will determine whether New Hampshire, Maine and Vermont and the other state legislatures considering legislation similar to the Prescription Information Law will be allowed to terminate the Petitioners' subject business activities, not based on otherwise harmful, illegal, unethical or improper conduct on the part of the Petitioners, but rather for a particular use of Petitioners' products – pharmaceutical detailing and direct marketing to physicians – by certain of their clients. The result is and would be unfair, unnecessary and overbroad.

II. The Prescription Information Law and the First Circuit's Ruling Fail to Consider the Varied Uses of Prescriber-Identifiable Information and the Varied Businesses and Industries Using and Relying on Prescriber-Identifiable Information, thus Wrongly Depriving those Users of those Uses.

The First Circuit's analysis of the value of the Petitioners' products and services, and particularly the prescriber-identifiable information, is both inconsistent and incomplete. The First Circuit acknowledges that the vast amount of information collected by the Petitioners has considerable utility for non-profit entities such as educational institutions, public interest groups, and law enforcement agencies. *IMS Health, Inc.* at 46. Nonetheless, later in the First Circuit's opinion, the majority states that "the challenged portions of the statute [the Prescription Information Law] principally regulate conduct and to the extent that the challenged portions impinge at all upon speech, that speech is of scant societal value." *Id.* at 52. The First Circuit's reasoning appears to place a higher or lower value on the Petitioners' products and services depending upon the nature and business of a customer's use thereof.

The First Circuit's narrow focus on pharmaceutical detailing prevented the majority from considering and valuing the varied uses and benefits of prescriber-identifiable information and the related products and services of the Petitioners. The First

Circuit, like the New Hampshire legislature, appears to focus its analysis on the assumed unpopularity of a certain group of end-users of the prescription reference files (i.e. pharmaceutical detailers), and the uses of the prescription reference files by such end-users (i.e. pharmaceutical detailing and direct marketing of prescription drugs). The First Circuit's opinion on the "true nature" of the Petitioners' motivations or concerns with regard to the Prescription Information Law, and the benefits of prescriber-identifiable information, fails to fully appreciate and acknowledge the societal importance of prescriber-identifiable information and the many uses of, and the many businesses and industries using and relying on, such information.

Prescriber-identifiable information has substantial value to the general public and the pharmaceutical industry well beyond pharmaceutical detailing or direct marketing of prescription drugs. The prescriber-identifiable information and the related products and services of the Petitioners are used by pharmaceutical and medical device manufacturers and others to evaluate, improve and develop pharmaceutical products and medical devices; to evaluate and identify trends and risks in the options for the treatment and care of the general public; to evaluate, improve and develop best practices for the pharmaceutical, medical and health care industries; to evaluate, improve and develop truthful communications regarding treatment options, trends, and best practice; and to address global health care issues.

For example, Amici and their respective membership and the pharmaceutical survey research industry of which Amici and their respective members are a part, utilize and rely on the prescriber-identifiable information and the related products and services of the Petitioners in conducting their research, including without limitation conducting surveys with identified physicians concerning various treatment and care options, best practices and trends; and concerning pharmaceutical products and medical devices utilized within a physician's practice. For example, in performing pharmaceutical survey research for a pharmaceutical or medical device manufacturer, the pharmaceutical survey researchers will often contact physicians from a list of physicians that may be provided by the manufacturer of the drug or device. The physician list and contact information are usually obtained by the manufacturer from third party data providers including the Petitioners. Pharmaceutical survey researchers do not perform any pharmaceutical detailing or direct advertising, marketing, or promotion of a manufacturer's products or devices; indeed the ethical codes of Amici and other marketing research trade organizations expressly prohibit the researchers from (a) marketing, selling or promoting products and services to the physicians and other data subjects and (b) identifying the surveyed physicians and other data subjects to the researchers' manufacturer clients; Amici's members in good standing are expected to zealously adhere to those prohibitions; instead the researchers seek solely the opinions, experiences and ideas of physicians

related to the subject matter of the survey. As noted above, pharmaceutical survey research and pharmaceutical marketing research themselves – the businesses of Amici – are benign, socially productive endeavors that heavily use the Petitioners' data and similar data. Depriving these various users of such data would unnecessarily, unfairly and wrongly injure their businesses and deprive the public of their valued services.

In sum, the First Circuit failed to consider the varied uses of prescriber-identifiable information that have a direct, beneficial and significant impact on the pharmaceutical, medical and health care industries and on the advancements and developments in health-care, which benefits and impact will be severely restricted, if not completely lost, if this Court fails to reverse the First Circuit's ruling.

III. The First Circuit's Ruling Establishes Precedents that Would Permit State and Federal Governments to Restrict and/or Censor Other Reliable, Legitimate and Truthful Information Subject to a Significantly Reduced Level of Judicial Scrutiny.

Other parties to this matter have extensively pleaded the relationship between the right to free speech under the First Amendment to the Constitution and legitimate restraints on commercial activities. Amici will not reiterate all of those arguments, but instead will focus on a particular aspect of them.

The First Circuit's classification of the collection, aggregation and sale of reliable, legitimate and truthful information as "conduct" instead of "speech" could drastically reduce the level of judicial scrutiny required to uphold any governmental regulation prohibiting or restricting the use of such information. As a result, the Prescription Information Law and other "conduct" based laws might be viewed by some legislatures and courts as not falling within the scope of First Amendment protection and the intermediate level of scrutiny, as set forth in *Central Hudson Gas & Electric Corporation v. Public Services Comm'n of New York*, 447 U.S. 557, 566 (1980). Instead such "conduct" based laws might be viewed as an "economic regulation", thus subject to the lowest level of judicial scrutiny, the rational basis test. *IMS Health, Inc.* at 54. Under the rational basis test, a governmental regulation would be upheld if it is reasonably related to any legitimate government interest. The governmental regulation would be afforded a presumption of validity, absent a showing that negates every conceivable basis supporting such governmental regulation. *Federal Communications Commission and the United States v. Beach Communications, et al.*, 508 U.S. 307, 313-314 (1993) (citing *Lyng v. Automobile Workers*, 485 U.S. 360, 370 (1988) and *Lehnhausen v. Lake Shore Auto Parts Co.*, 410 U.S. 356, 364 (1973)).

The First Circuit's ruling thus could enable state and Federal governments to severely restrict, and censor, the use, transfer, disclosure and sale of other types of reliable, legitimate and truthful information

with little judicial scrutiny. State and Federal Governments could be able to capriciously restrict and censor information and data transactions, exchanges, transfers or uses that are unpopular but not harmful, illegal, unethical, or immoral.

The end result of unchecked governmental regulation on reliable, legitimate and truthful information would be devastating for Amici and its membership and any other business or industry relying on the availability of reliable, truthful and legitimate information in the performance of its business or activities. The unavailability of such information would severely limit the Amici's and their respective members' and such other businesses' and industries' ability to serve not only their direct clients, but also their indirect clients, the general public.

CONCLUSION

For the above stated reasons, Amici Curiae respectfully request that this Court grant the Petitioners' writ of certiorari and reverse the First Circuit's ruling and invalidate the Prescription Information Law.

Respectfully submitted,

DUANE L. BERLIN

Counsel of Record

E. BARRY LYON

LEV & BERLIN, P.C.

200 Connecticut Avenue

5th Floor

Norwalk, CT 06854

(203) 838-8500

MICHAEL SLOTZNICK

1020 Little Shiloh Road

West Chester, PA 19382

(484) 887-0497

Counsel for Amici Curiae

Pharmaceutical Marketing

Research Group, Inc.

Counsel for Amici Curiae

Council of American

Survey Research

Organizations, Inc.

APPENDIX A

App. 1

CASRO – Who We Are – What We Do

Founded in 1975, the Council of American Survey Research Organizations (CASRO) represents over 300 companies and research operations in the United States and abroad.

CASRO is the “Voice and Values” of the survey research industry.

- We promote a rigorous code of conduct that enhances the image of survey research and protects the public's rights and privacy
- We advocate our industry's effective self-regulation when legislators propose bills that threaten legitimate survey research
- We champion legitimate research companies and marginalize disreputable research “pretenders” who threaten to tarnish the industry's reputation and alienate respondents

CASRO requires members to adhere to the CASRO Code of Standards and Ethics for Survey Research, a tough, internationally-cited set of standards, which has long been the benchmark for the industry.

CASRO provides its members with numerous benefits, including access invaluable industry data, and superb staff training and networking opportunities at workshops and conferences throughout the country.

App. 2

CASRO has achieved unique status among all North American associations by serving as an active representative on numerous global initiatives and as chief liaison with several leading international associations.

CASRO's "Research Career Development" initiative reaches out to colleges and universities with information and resources to attract the best and brightest students and to make the survey research profession a career of choice.

<http://www.casro.org/whatis.cfm>

4/23/2009
